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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,719	02/15/2002	Victorio C. Rodriguez	PS 00-07-01	2639

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DONALD A BERGQUIST
PATENT SERVICES COMPANY
P O BOX 360590
STRONGSVILLE, OH 441360010

EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

10/077,719

Applicant(s)

RODRIGUEZ, VICTORIO C.

Examiner

JOHN D PAK

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: .

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Claims 2-4 and 11 have been canceled. Claims 1 and 5-10 are now pending in this application.

Claims 1 and 5-10 are generic to a plurality of disclosed patentably distinct species comprising a non-enzyme compound that increases the presence of cell-specific carbonic anhydrase enzymes in the brain, such as for example, sulfonylamido derivatives of histamine, NSAID or zinc. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

It is noted that the cancellation of the above noted claims was in response to a telephonic restriction requirement that was made by the Examiner on 1/8/2003. See the interview summary record of Paper No. 3. The Examiner also required an election of a species (same as above). Applicant's attorney, Mr. Bergquist elected the invention Group II on 1/8/2003. In the reply and amendment of 1/22/2003, Mr. Bergquist elected sulfonylamido derivatives of histamine is the single disclosed species. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a))

Applicant is advised that in claim 10, "sufonylamido" is a misspelling. There is a missing "l" after "su".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior

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art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Tozer et al., EP 680960 and Medline abstract 1999441621.

Tozer et al. teach that sulfonylamido derivatives of histamine are histamine H₃ receptor antagonists. See pages 3103 and 3107 (last paragraph).

EP 680960 teaches that histamine H₃ receptor antagonists are used to treat Alzheimer's disease (p. 3, lines 31-33; p. 18, lines 35-36). Medline abstract 1999441621 teaches also that H₃ receptor antagonists are suggested for treating dementia.

The difference between the claimed invention and the cited references is that the references do not (i) specifically disclose sulfonylamido derivatives of histamine for conditions of aging such as Alzheimer's Disease, and (ii) specifically disclose the increasing effect of sulfonylamido derivatives of histamines for cell-specific carbonic anhydrase enzyme in the brain.

However, it is the Examiner's position that one having ordinary skill in the art would have been motivated from the known H₃ receptor antagonistic activity of sulfonylamido derivatives of histamine to administer such derivatives to treat Alzheimer's disease and dementia. While the actual mechanism of increasing the presence of cell-specific carbonic anhydrase enzymes in the brain is not elucidated by the cited references, such mechanism would have necessarily have been obtained after administering the very same sulfonylamido derivatives

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of histamine. Since the same substance is administered to patients with the same condition, the same effect must be obtained. Applicant's pharmaceutically effective, non-toxic amount language is noted, but there is insufficient evidence that an amount that provides H₃ receptor antagonistic activity that is effective to treat Alzheimer's and dementia is not within or overlaps with an amount that increases the presence of cell-specific carbonic anhydrase enzymes in the brain to treat Alzheimer's and dementia. In the absence of such evidence, treatment of Alzheimer's and dementia with H₃ receptor antagonistic activity is deemed to meet the claim feature.

Modes of administration such as IM or IV injection or ingestion are typical of drug delivery, and such modes of administration would have been well within the skill of the ordinary skilled artisan in this medical field.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the teachings of the cited references.

For these reasons, no claim can be allowed at this time.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Friday from 7:30 AM to 4 PM.


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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.



JOHN PAK
PRIMARY EXAMINER
GROUP 1000